K062238

Tytan Medical Corp.
6F-4, No.11, Wu-Chun 1Rd,
Hsin Chuang, Taipei, 24892, Taiwan, R. O. C.
Tel : 886-2-2298-9579 Fax : 886-2-2298-9578
E-mail : SERVICES@TYTAN.COM
Internet : www.tytan.com.tw

SEP 2 1 2006

3. SUMMARY OF SAFETY AND EFFECTIVENESS
(According to 21 CFR 807.92)

DATE OF SUBMISSION:	July 30, 2006
SUBMITTER:	General Manager, Mr. MICHAEL SHIEH TYTAN MEDICAL CORP. 6F-4, No.11, Wu-Chun 1 Rd., Hsin Chuang, Taipei, 24892, Taiwan TEL: 886-2-22979579 FAX: 886-2-22989578
ESTABLISHMENT REGISTRATION NO:	9616940
OFFICIAL CONTACT:	Dr. JEN, KE-MIN ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY NO 58, FU-CHIUN ST. HSIN-CHU CITY, CHINA (TAIWAN) 30067 TEL: 886-3-5208829 FAX:886-3-5209783 EMAIL: CEIRS.JEN@MSA.HINET.COM
TRADE NAME:	TYTAN BLOOD PRESSURE CUFF
COMMON/USUAL NAME:	BLOOD PRESSURE CUFF
CLASSIFICATION NAME:	CUFF, BLOOD PRESSURE (CFR870.1120)
CLASSIFICATION PANEL:	CARDIOVASCULAR
PREDICATED DEVICE:	TRICOT BLOOD PRESSURE CUFF (K051539)
INTENDED USE:	The TYTAN blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in newborn through large adult sizes

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DEVICE DESCRIPTION:

The TYTAN blood pressure cuff is a device that has an inflatable bladder in an inelastic sleeve (cuff) with a mechanism for inflating and deflating the bladder. The TYTAN blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in newborn through large adult sizes. Each cuff will be packaged in a polyethylene bag.

COMPARISON WITH PREDICATE DEVICE:

ITEM	SUBJECT DEVICE	PREDICATE DEVICE
NAME	TYTAN Medical Corp. TYTAN BLOOD PRESSURE CUFF	YA HORNG Electronic Co., Ltd. TRICOT BLOOD PRESSURE CUFF (K051539)
INTENDED USE	INDIRECT MEASUREMENT OF BLOOD PRESSURE	INDIRECT MEASUREMENT OF BLOOD PRESSURE
ANATOMICAL SITES OF USE	UPPER ARM	WRIST
INTENDED POPULATION	NEWBORN – LARGE ADULT	CHILD- LARGE ADULT
LABELING	SEE SECTION 6	SEE SECTION 5
OUTER MATERIAL	NYLON FABRIC OR POLYESTER	NYLON FABRIC OR COTTON
BLADDER MATERIAL	LATEX	LATEX
CUFF CLOSURE	VELCRO	VELCRO
PRESSURE LIMITS	0 -300 mmHg	0 -300 mmHg
USABLE LIFE	10,000 INFLATION	10,000 INFLATION
NUMBER OF TUBES	1 and 2	1 and 2

PERFORMANCE DATA

The TYTAN blood pressure cuff was compared to the TRICOT blood pressure cuff to confirm its functional and physical performance characteristics were equivalent. The AAMI SP9:1994 standard was used to select the relevant performance attributes to measure. The cuffs were equivalent in performance in regards to DIMENSION, PRESSURE CAPACITY, and CUFF CLOSURE as required under the SP9 standard. Though the outer materials have certain difference, the subject device passes three Biocompatibility tests, and they are substantially equivalent in this respect.

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CONCLUSION

In accordance with the FDA 21 CFR 807 and based on the information provided in this premarket notification, TYTAN Medical Corp. concludes that the TYTAN Blood Pressure Cuff is safe, effective and substantially equivalent to the TRICOT BLOOD PRESSURE CUFF (K051539) predicate device as described herein and meets the relevant requirements of ANSI/AAMI SP9-1994.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 1 2006

Tytan Medical Corp.
c/o Dr. Jen, Ke-Min
ROC Chinese-Euorpean Industrial Research Society
No. 58 Fu-Chiun St.
Hsin-Chu City, 30067
TAIWAN, REPUBLIC OF CHINA

Re: K062238
Trade Name: Tytan Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: August 21, 2006
Received: August 23, 2006

Dear Dr. Jen, Ke-Min:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tytan Medical

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Indications for Use

510(k) Number: K 062238

Device Name: TYTAN MEDICAL CORP.
TYTAN BLOOD-PRESSURE CUFF

Indications for Use:

The TYTAN blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in newborn through large adult sizes.

Prescription Use _____ AND/OR Over-The-Counter Use √
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K062238